may influence transplant program-specific results. Such data shall also include such other cost or performance information as the Secretary may specify, including but not limited to transplant program-specific information on waiting time within medical status, organ wastage, and refusal of organ offers. These data shall also be presented no more than six months later than the period to which they apply;

(v) Respond to reasonable requests from the public for data needed for bona fide research or analysis purposes, to the extent that the OPTN's or Scientific Registry's resources permit, or as directed by the Secretary. The OPTN or the Scientific Registry may impose reasonable charges for the separable costs of responding to such requests. Patient-identified data may be made available to bona fide researchers upon a showing that the research design requires such data for matching or other purposes, and that appropriate confidentiality protections, including destruction of patient identifiers upon completion of matching, will be followed. All requests shall be processed expeditiously, with data normally made available within 30 days from the date of request;

(vi) Respond to reasonable requests from the public for data needed to assess the performance of the OPTN or Scientific Registry, to assess individual transplant programs, or for other purposes. The OPTN or Scientific Registry may impose charges for the separable costs of responding to such requests. An estimate of such charges shall be provided to the requester before processing the request. All requests should be processed expeditiously, with data normally made available within 30 days from the date of request; and

(vii) Provide data to an OPTN member, without charge, that has been assembled, stored, or transformed from data originally supplied by that member.

(2) An organ procurement organization or transplant hospital shall, as specified from time to time by the Secretary, submit to the OPTN, to the Scientific Registry, as appropriate, and to the Secretary information regarding transplantation candidates, transplant recipients, donors of organs, transplant program costs and performance, and other information that the Secretary deems appropriate. Such information shall be in the form required and shall be submitted in accordance with the schedule prescribed. No restrictions on subsequent redisclosure may be imposed by any organ procurement organization or transplant hospital.

(c) *Public access to data.* The Secretary may release to the public information collected under this section when the Secretary determines that the public interest will be served by such release. The information which may be released includes, but is not limited to, information on the comparative costs and patient outcomes at each transplant program affiliated with the OPTN, transplant program personnel, information regarding instances in which transplant programs refuse offers of organs to their patients, information regarding characteristics of individual transplant programs, information regarding waiting time at individual transplant programs, and such other data as the Secretary determines will provide information to patients, their families, and their physicians that will assist them in making decisions regarding transplantation.

[63 FR 16332, Apr. 2, 1998, as amended at 64 FR 56661, Oct. 20, 1999]

§ 121.12 Advisory Committee on Organ Transplantation.

The Secretary will establish, consistent with the Federal Advisory Committee Act, the Advisory Committee on Organ Transplantation. The Secretary may seek the comments of the Advisory Committee on proposed OPTN policies and such other matters as the Secretary determines.

[64 FR 56661, Oct. 20, 1999]

§ 121.13 Definition of Human Organ Under section 301 of the National Organ Transplant Act, as amended.

''Human organ,'' as covered by section 301 of the National Organ Transplant Act, as amended, means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, skin, and intestine,

including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract.

[72 FR 10619, Mar. 9, 2007]

PART 124—MEDICAL FACILITY CONSTRUCTION AND MODERNIZATION

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AUTHORITY: Secs. 215, 1602, 1625, Public Health Service Act (42 U.S.C. 216, 300o–1, 300r), unless otherwise noted.

SOURCE: 42 FR 62270, Dec. 9, 1977, unless otherwise noted.

Subpart A—Project Grants for Public Medical Facility Construction and Modernization

§ 124.1 Applicability.

The regulations of this subpart are applicable to grants under section 1625 of the Public Health Service Act for construction and modernization projects designed to:

(a) Eliminate or prevent imminent safety hazards as defined by Federal, State or local fire, building, or life safety codes or regulations, or

(b) Avoid noncompliance with State or voluntary licensure or accreditation standards.

§ 124.2 Definitions.

As used in this subpart:

(a) *Act* means the Public Health Service Act, as amended.

(b) *Construction* means construction of new buildings and initial equipment of such buildings and, in any case in